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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,105	12/04/2001	Thomas J. Slaga	Enlarged Prostate-CIP	3918

7590 05/16/2003

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
1614	<i>S</i>

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>10/004,105</b>	Applicant(s) <b>Slaga et al.</b>
	Examiner <b>Phyllis G. Spivack</b>	Art Unit <b>1614</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on Feb 10, 2003
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 8-10 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 8-10 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All b)  Some\* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
  - a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

Art Unit: 1614

Applicants' Amendment filed February 10, 2003, Paper No. 7, is acknowledged. Claims 1-7 are canceled. New claim 10 is presented. Accordingly, claim 8-10 are now under consideration.

An Information Disclosure Statement filed October 15, 2002, Paper No. 5, is further acknowledged and has been reviewed to the extent a publication date is provided for each reference.

A new title and A Brief Description of the Drawings are noted.

Subsequent to the cancellation of claims 1-7, the objection under 37 C FR 1.75( c) and the rejections of record under 35 U.S.C. 112, second paragraph, and under 35 U.S.C. 102(a) as being anticipated by Sukumaran et al., Indian J. Physiol. Pharmacol. are moot. To the extent the canceled claims are included, the rejections of record under 35 U.S.C. 102(a) as being anticipated by Mukhopadhyay et al., U.S. Patent 5,958,892, and Liao et al., WO 99/22728, and Defeudis, F.V., WO 96/30012, are moot.

Applicants' arguments with respect to claim 8, rejected under both 35 U.S.C. 102 as being anticipated by Mukhopadhyay et al., U.S. Patent 5,958,892, and 35 U.S.C. 102(b) as being anticipated by Defeudis, F.V., WO 96/30012; and claims 8 and 9 under 35 U.S.C. 103 as being obvious under 35 U.S.C. 103 over both Sukumaran et al., and Mukhopadhyay et al., have been considered but are moot in view of the new grounds of rejection.

In the last Office Action claim 8 was rejected under 35 U.S.C. 102(a) as being anticipated by Liao et al., WO 99/22728. It was asserted Liao teaches the administration of eugenol to treat

Art Unit: 1614

benign prostatic hyperplasia or prostatitis, conditions characterized by enlargement of the prostate, but non-cancerous conditions. See claim 7, page 32.

Applicants' arguments are directed to the administration of eugenol against prostate cancer. Despite the inclusion in the rejection of the non-cancerous condition prostatitis, there is no specific response in Paper No. 7 to this condition other than a conclusionary statement that eugenol "shows promise in treating and preventing enlarged prostate conditions".

Accordingly, the rejection of record of claim 8 under 35 U.S.C. 102(a) as being anticipated by Liao et al., WO 99/22728, is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Smith, R. et al., WO 96/40150.

Smith teaches the administration of 2-methoxyestradiol as a steroid metabolite with no biological activity that acts as an antagonist to the sex hormone-binding globulin receptor for use in the treatment of benign prostatic hyperplasia, a non-cancerous condition. See page 4, lines 17-19, as well as Table 2 on page 22.

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over both Smith, R. et al., WO 96/40150, and Liao et al., WO 99/22728.

Smith teaches the administration of 2-methoxyestradiol, as a steroid metabolite with no biological activity, that acts as an antagonist to the sex hormone-binding receptor for use in the treatment of benign prostatic hyperplasia, a non-cancerous condition. See page 4, lines 17-19, as well as Table 2 on page 22. Liao teaches the administration of eugenol to treat benign prostatic hyperplasia or prostatitis, conditions characterized by enlargement of the prostate, but non-cancerous conditions. See claim 7, page 32. Both references are directed to treating an enlarged, non-cancerous condition of the prostate. One skilled in the art would have been motivated to prepare a therapeutic agent comprising eugenol in combination with 2-methoxyestradiol to treat non-cancerous conditions of the prostate gland in mammals in view of the combined teachings of Smith and Liao. Such would have been obvious in the absence of evidence to the contrary because it is generally *prima facie* obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. In re Kerkhoven 205 USPQ 1069 (CCPA 1980).

Art Unit: 1614

Obviousness does not require absolute predictability but only the reasonable expectation of success. Specific statements in the references themselves that would spell out the claimed invention are not necessary to show obviousness. Questions of obviousness involve not only what the references expressly teach, but what they would collectively suggest to one of ordinary skill in the art.

It is noted the Figures and the disclosure provide support for an advantageous therapeutic effect resulting from the combination of 2-methoxyestradiol with eugenol in an a laboratory model of the cancer cell line LNCaP human prostate tumor. However, the data is not commensurate in scope with the present claims.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide support in claims 8 and 10 for "preventing the development of" enlarged, non-cancerous prostate glands.

Following "in mammals" in claims 8 and 10, the recitation -- in need thereof -- should be considered.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

May 13, 2003

*Phyllis Spivack*

PHYLLIS SPIVACK  
PRIMARY EXAMINER